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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/583,200	05/30/2000	John D Fikes	018623-015720US	1443

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/583,200	FIKES ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-169* is/are pending in the application.

4a) Of the above claim(s) *38-40,42-53,55-63,66,69,72 and 74-169* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37,41,54,,64,65,67,68,70,71,73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election with traverse of RLLQETELV and composition containing a CTL epitope in the reply filed on 11/12/02 and 6/6/03 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. Regarding applicants comments in the response filed 11/12/02 about MPEP 803.04, the claimed inventions are not nucleic acids. The searching of additional peptides would place a serious burden on the Examiner. Regarding applicants comments in the response filed 6/6/03, the elected species will be interpreted as per the originally filed claims (aka a composition containing the claimed peptide and an additional CTL epitope). The species enunciated in the previous Office Action are chemically and functionally distinct.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 38-40,42-53,55-63,66,69,72,74-169 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/12/02 and 6/6/03.

3. Claims 37,41,54,64,65,67,68,70,71,73 are under consideration.

4. Non-English language publications on the IDS of 3/19/03 have only been considered for their English language content.

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the oath has a priority claim to a single application, whilst the amended priority claim in the specification now claims priority to a plethora of previously not claimed applications.

6. Applicant is required to update the status of all US applications disclosed in the instant application.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 37,41,54,64,65,67,68,70,71,73 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,602,510. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the two sets of claims differ in scope, both sets of claims recite the peptide RLLQETELV and disclose compositions containing said peptide and other CTL epitopes (aka the other peptides recited in claim 1). The composition of claim 2 would also contain tissue culture media or PBS which is a pharmaceutically acceptable carrier.

9. Claims 37,41,54,64,65,67,68,70,71,73 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/149915. Although the conflicting claims are not identical, they are not patentably distinct from each other because the two sets of claims while differing in scope both encompass the claimed compositions or vaccines containing RLLQETELV.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 65,67,71,73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed vaccine or pharmaceutical compositions. The specification does not disclose how to use the instant inventions for the in vivo treatment of cancer in humans. The peptide recited in the claims is derived from the HER2/neu (aka c-ERB2) protein that is associated with human tumors. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant inventions disclosed in the specification is the in vivo treatment of cancer in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence as to how the instant invention could be used in vivo in humans. Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir.

1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

Regarding Wands factors 4,5,7,8, the instant invention is a vaccine or pharmaceutical composition for treatment of human cancer. The substantial/real life use for the claimed invention is in vivo treatment of cancer in humans. Tumor peptide vaccines are currently not used routinely in the treatment of human cancer. In fact, there are currently no approved tumor vaccines for use in the United States (see June, page 2, lines 6-9). This statement is made in a paper published in 2005 wherein the claimed invention claims priority to an application filed in 1993. Thus, twelve years after the earliest effective filing date of the instant application it is still unclear whether any particular peptide can be used as tumor vaccine.

Thus, the state of the art is that it is unpredictable whether the claimed peptides can be used in vivo in humans to treat cancer. As per Wands factor (8), the claims encompass the treatment of human cancer using the claimed compositions. The prior art recognizes that T cell responses to T cell antigens are MHC restricted (eg. the peptide is recognized in the context of a self MHC/peptide complex, see Yewdell et al., page 53). The instant claims are not limited to a particular set of alleles which have been shown to bind the peptide recited in the claim. The specification indicates that the peptide recited in the claims would only bind several HLA allotypes (see Tables) wherein there are at least a hundred known alleles. Thus, it appears that the claimed method could not be used in most humans because they do not express an HLA allele which binds the peptide recited in the claims. In addition, the prior art discloses that prior to use in vivo in humans, it is appropriate to test whether a peptide generates human CTL. Such evidence is not provided in the specification. Furthermore, Yewdell et al. indicate that MHC binding in itself is not evidence that a peptide will actually generate a CTL response (for example see pages 56 and 57).

Regarding Wands factors 1-3, the specification provides no experimental data regarding the in vivo use of the peptide recited in the claims. There is also no evidence provided that the peptide recited in the claimed method can be recognized by human CTL. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.).

It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

12. Regarding claim 37, whilst the claim discloses an isolated peptide of 9-11 amino acids comprising the oligopeptide RLLQETELV, claim 57 indicates that the peptide of claim 37 can also contain additional amino acids (the size of the T helper peptide and RLLQETELV would be greater than 9-11 amino acids). However, the definition of peptide in the specification, page 11, last paragraph, continued on page 12, indicates that the claimed molecule would not read on intact HER-2/neu, because said molecule is greater than 600 amino acids (it is 185 kD). The aformentioned definition of peptide and said length limitation are not disclosed in the parent applications to which priority is claimed. Therefore, regarding the application of prior art, the effective filing date of the instant application is the filing date of the instant application. The language "peptide is" is considered open in scope.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 37,41,54,64,65,67,68,70,71,73 are rejected under 35 U.S.C. 102(b) as being anticipated by Grey et al. (WO 94/020127 A1).

Grey et al. disclose the claimed peptide (see page 100) and the claimed compositions/vaccines containing said peptide (see pages 23-27). The composition can contain additional CTL peptides (see claims 19-21, wherein the claimed peptide is encompassed by the generic peptide recited in claim 19 and page 26).

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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